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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT FRIGG and PASCAL SCHORI[1]

Appeal 2012-003119
Application 12/092,748
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and ERICA A. FRANKLIN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an intramedullary implant and guide sleeve, which have been rejected as anticipated or obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] Appellants identify the Real Party in Interest as Synthes, Inc. (Appeal Br. 2).

STATEMENT OF THE CASE

Claims 19-39 are on appeal. Claims 19 and 28 are illustrative and read as follows (emphasis added):

> 19. A device for implantation in a medullary space of a bone via a curved insertion path, comprising:
>
> a curved proximal portion extending along an arc substantially similar to an arc of the curved insertion path, the proximal portion including a coupling arrangement at a proximal end thereof adapted to couple to a tool for one of intramedullary implantation and explantation; and
>
> a flexible distal portion extending from a distal end of the proximal portion, *the distal portion extending substantially straight in an unstressed state and having flexibility sufficient to permit bending along the arc of the insertion path substantially without permanent deformation*.
>
> 28. A guide sleeve for insertion of an implant into a medullary space of a bone, comprising:
>
> a distal portion which, when the guide sleeve is in an operative position, extends into a medullary space of a bone along a curved path;
>
> a proximal portion which, when the guide sleeve is in the operative position, extends out of a body to a proximal end which remains accessible to a user;
>
> an intermediary portion coupled between the proximal and distal portions, *the intermediary portion extending along a predetermined curve* corresponding to a curve along which an intramedullary implant is to be inserted through the bone into the medullary space; and
>
> a lumen extending through the guide sleeve from a proximal opening at the proximal end to a distal opening at a distal end of the distal portion.

The claims stand rejected as follows:

• Claims 19, 21, 24, and 25 under 35 U.S.C. § 102(b) as anticipated by Phillips[2] (Answer 5);

• Claims 28, 29, and 35 under 35 U.S.C. § 102(b) as anticipated by Durham '392[3] (Answer 6);

• Claims 30-33 under 35 U.S.C. § 103(a) as obvious based on Durham '392 (Answer 7);

• Claim 20 under 35 U.S.C. § 103(a) as obvious based on Phillips and Camino[4] (Answer 8);

• Claim 22 under 35 U.S.C. § 103(a) as obvious based on Phillips and Lewallen[5] (Answer 8);

• Claim 23 under 35 U.S.C. § 103(a) as obvious based on Phillips, Lewallen, and DiPietropolo[6] (Answer 9);

• Claims 26 and 27 under 35 U.S.C. § 103(a) as obvious based on Phillips and Durham '595[7] (Answer 10);

• Claim 34 under 35 U.S.C. § 103(a) as obvious based on Durham '392 and Jones[8] (Answer 11); and

• Claims 36-39 under 35 U.S.C. § 103(a) as obvious based on Phillips and Durham '392 (Answer 11).

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[2] Phillips, US 2002/0111629 A1, Aug. 15, 2002.
[3] Durham, US 6,074,392, June 13, 2000.
[4] Camino, US 6,656,187 B1, Dec. 2, 2003.
[5] Lewallen, US 2004/0088056 A1, May 6, 2004.
[6] DiPietropolo, US 4,751,922, June 21, 1988.
[7] Durham et al., US 6,168,595 B1 Jan. 2, 2001.
[8] Jones et al., US 2004/0193267 A1, Sept. 30, 2004.

I.

The Examiner has rejected claims 19, 21, 24, and 25 as anticipated by Phillips (Answer 5). The Examiner finds that Phillips discloses a device meeting all of the limitations of claim 19, including "a flexible distal portion (34) extending from a distal end of the proximal portion, the distal portion extending substantially straight in an unstressed state (*see* Fig. 5) and having flexibility sufficient to permit bending along the arc of the insertion path substantially without permanent deformation (*see* Fig. 3)" (*id*.).

Appellants argue that "Phillips shows an intramedullary nail including a distal portion that is curved along a length thereof in an unstressed state to conform to a femoral curvature" (Appeal Br. 7) and that "that Phillips neither shows nor suggests that the distal end section 34 extends substantially straight in an unstressed state" (*id*. at 8).

We agree with Appellants that the Examiner has not shown that the device disclosed by Phillips meets all of the limitations of claim 19. Claim 19 requires a distal portion (a) "extending substantially straight in an unstressed state" and (b) "having flexibility sufficient to permit bending along the arc of the insertion path substantially without permanent deformation."

> Phillips discloses an intramedullary nail (Phillips 1, ¶ 9) in which
>
> the central section . . . is curved in the sagital [sic] plane to generally follow the curvature of a femur. . . . The proximal and distal end sections are each bent laterally to one side of the central section. The side to which the proximal and distal end sections are bent depends on whether the nail will be used in a right or left femur.

(*Id*. at 1-2, ¶ 10.)

Thus, in Phillips' device, the distal portion is bent to one side or the other, depending on whether it is intended for use in a left or right femur, relative to the central section. The Examiner argues, however, that the

> purpose of the bend (74) between the distal portion and central portion[ ] of the nail is so that the distal portion can be bent from its unstressed, straight position to a curved position to follow the insertion path, and thus, make entry of the distal portion easier (see Phillips, paragraph [0034]). Thus, in an unstressed state, the distal portion of the nail extends substantially straight.

(Answer 14.)

We disagree with the Examiner's reasoning. Phillips describes its device has having permanently bent proximal and distal end sections. Although Phillips states that the nail "may be custom bent by the surgeon just prior to use" (Phillips 3, ¶ 32), it also describes "a manual bending device" (*id*. at 3, ¶ 35) that is required to carry out the bending. The Examiner has not provided evidence sufficient to support the finding that Phillips' device includes a distal portion that both extends straight in an unstressed state and has sufficient flexibility to permit bending without permanent deformation.

Claims 21, 24, and 25 depend on claim 19. We therefore reverse the rejection of claims 19, 21, 24, and 15 as anticipated by Phillips.

II.

The Examiner has rejected claims 28, 29, and 35 as anticipated by Durham '392 (Answer 6). The Examiner finds that Durham '392 discloses a guide sleeve meeting all of the limitations of claim 28, including an "intermediary portion extending along a predetermined curve corresponding

to a curve along which an intramedullary implant is to be inserted through the bone into the medullary space (see Fig. 4c)" (*id*.).

Appellants argue that Durham '392 "discloses a flexible reamer which conforms to any path through which it is slid such that the flexible reamer does not extend along a predetermined curve" (Appeal Br. 9).

We agree with Appellants that the Examiner has not shown that the device disclosed by Durham '392 includes an "intermediary portion extending along a predetermined curve," as required by claim 28. Durham '392 discloses "a flexible drill or reamer . . . which includes a hollow flexible drill or reamer element **16** in which the curved pin **12** is received and which bends or flexes so to accommodate the curvature of the pin" (Durham '392, col. 4, ll. 47-50). Durham '392 states that the "curvature of the pin **12** is preset and fixed and the pin **12** is inserted into the bone to provide a guide path for a drill or reamer so as to enable insertion of a fixation device such as an intermedullary rod or nail" (*id*. at col. 4, ll. 41-45).

Thus, the reamer (guide sleeve) described by Durham '392 does not have a predetermined curve, as required by claim 28, but instead is flexible and bends to accommodate the curvature of a pin that provides the guide path for the reamer.

The Examiner reasons that

> [g]iving the term "predetermined" its broadest reasonable interpretation . . . , the claim only requires that the intermediary portion of the guide sleeve achieve[s] a curved shape that is determined ahead of time for it to have. The intermediary portion of the sleeve of Durham ['392] is capable of achieving such a predetermined shape, as shown in Fig. 4C, for example. The claim does not require that [the] intermediary portion of the guide sleeve have a curve prior to insertion.

(Answer 15.)

We disagree with the Examiner's reasoning. The Specification consistently describes the disclosed guide sleeve as having a fixed, curved shape. *See* Spec. 3:5-9 ("[T]he guide sleeve . . . consists of a tube which forms a circular arc like a circular sector. . . . [T]he diameter of the tube, the diameter of the circular arc as well as the length of the circular arc is dependent on the application."); 4:22-24 ("The guide sleeve . . . is provided with at least one curvature in the intermediary piece."); 5:11 ("[T]he radius R_F of the circular arc like curvature of the intermediary piece is equal to the radius R_I of the circular arc like curvature of the first end portion of the implant.").

Thus, we agree with Appellants that the broadest reasonable interpretation of "a predetermined curve," as required by claim 28, is a "curvature that exists prior to insertion of the guide sleeve into the insertion path of the bone" (Appeal Br. 9). The flexible reamer disclosed by Durham '392, which bends to accommodate the curve of a curved pin, lacks this property, and therefore does not meet all of the limitations of claim 28.

Claims 29 and 35 depend on claim 28. We therefore reverse the rejection of claims 28, 29, and 35 as anticipated by Durham '392.

III.

The Examiner has rejected claims 20, 22, 23, 26, 27, 30-34, and 36-39 as obvious based Phillips, Durham '392, and additional prior art (Answer 7-13). The Examiner relies on Phillips and Durham '392 as disclosing the implant of claim 19 and the guide sleeve of claim 28, respectively, and finds

that the cited references collectively would have made obvious the limitations of the rejected claims.

Claims 36 and 38 are the other independent claims on appeal and include the same relevant limitations as claims 19 and 28. As discussed above, Phillips and Durham '392 do not disclose those limitations, and the Examiner has not provided a reasoned basis for concluding that the missing limitations would nonetheless have been obvious. We therefore reverse the rejections of claims 36 and 38.

Claims 20, 22, 23, 26, 27, 30-34, 37, and 39 depend on one of claims 19, 28, 36, or 38. We therefore reverse the rejections of these claims as well.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED

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